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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/031,938	07/22/2002	Srinivas Kaveri	TJK/209	8718

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SEYFARTH SHAW
55 EAST MONROE STREET
SUITE 4200
CHICAGO, IL 60603-5803

EXAMINER	
PATTERSON, CHARLES L JR	
ART UNIT	**PAPER NUMBER**
1652	

DATE MAILED: 09/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/031,938	KAVERI ET AL.	
	Examiner	Art Unit	
	Charles L. Patterson, Jr.	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *2/3/03,/2/5/03, 2/7/03, 5/2/03 & 7/15/04*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *86-154* is/are pending in the application.

4a) Of the above claim(s) *124-140 and 144-150* is/are withdrawn from consideration.

5)☒ Claim(s) *117-120* is/are allowed.

6)☒ Claim(s) *86,106,108-116,121-123,141-143 and 151-154* is/are rejected.

7)☒ Claim(s) *87-105 and 107* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Applicant's election with traverse of Group I, claims 86-110 and 151-154 in the reply filed on 7/15/04 is acknowledged. The traversal is on the ground(s) that the rules of unity of invention under 35 USC § 371 and PCT rule 13 have not been met. This is not found persuasive because of the reasons discussed *infra*:

(1) Applicants argue that the European searching authority when making the search has already determined that there was unity of invention. It is pointed out that rules for examination of patents in Europe and the U.S. vary widely and what is done in one jurisdiction is not binding upon the other jurisdiction. This is a 35 USC § 371 U.S. application and will be examined according to U.S. rules and practice.

(2) Applicants further argue that "[a]ccording to Article 27, paragraph of the PCT, it is not possible for a National Office, as the Examiner attempts here, to add additional requirements to those of the PCT treaty and implementing Rules. The instant paragraph states "(1) No national law shall require compliance with requirements relating to the form or contents of the international application different from or additional to those which are provided for in this Treaty and the Regulations." The instant unity of invention requirement does not relate to "form or contents of the international application different from or additional to those which are provided" by the PCT treaty and rules. It relates to examination rules and unity of invention/restriction practice in the U.S. Therefore this argument has no bearing upon the instant discussion.

(3) Finally applicants argue that the examiner has applied Rule 13 incorrectly in that the "single inventive concept" is an anti-Factor VIII allo-antibody which is capable of degrading Factor VIII in a mammal. This is not found persuasive because the groups that will be examined, listed *infra*,

are drawn to methods of determining the presence of anti-Factor VIII allo-antibodies, anti-Factor VIII antibodies, individual amino acid sequences and analogs of them, a method of neutralizing catalytic anti-Factor VIII allo-antibodies and an anti-Factor VIII allo-antibody inhibitor. The remaining claims are drawn to methods of treatment and pharmaceutical compositions. These are additional methods and the compound used for them than the methods that will be examined.

The requirement is still deemed proper and is therefore made FINAL.

After further consideration the examiner will examine claims 86-123, 141-143 and 151-154. Claims 124-140 and 144-150 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 7/15/04.

This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 because at least the sequences on page 5, 7, 20, claims 111-113, 121-123, 135-137, 141-143 and 148-150 are not labeled as to SEQ ID NO. Also, there is reference made to specific residues in the sequence of Factor VIII but the sequence of this protein is not included in the CRF or written sequences. Because the application could be

examined without this disclosure this has been done but it must be included in the patent file before any patent can be issued.

The disclosure is objected to because of the following informalities:

The specification refers to figures but no figures were submitted with application filed on 1/22/02. However, the transmittal letter filed on that date states that a copy of the application is attached and a 35 USC § 371 case the file is supposed to be identical with the PCT application, which contains the figures. The patent office apparently lost the drawings filed with this application. The easiest way to put the figures into this 371 application is for applicants to include them in an amendment. This would not be new matter.

There is no recitation of "Figure 3 A-C" in the Brief Description Of The Drawings. Neither is there an explanation of the different lanes or the conditions in A-C of the instant figure. Applicants should be careful not to include "new matter" in adding this information.

Appropriate correction is required.

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 111-116, 141-143 and 151-154 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. In U.S. patent practice there must be some indication of the intervention of the "hand of man" in product claims. Adding "isolated" or a similar term to the instant claims would overcome this rejection.

Claims 111-113 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility.

The instant claims are drawn to specific amino acid peptides. Presumably these are the regions of cleavage of Factor VIII by the allo-antibody of the claims. There is not disclosed or asserted any specific or substantial use for these peptides. Presumably if the peptides were added to the Factor VIII/allo-antibody mix they would be cleaved and thus would not be inhibitors of the reaction. The statement on page 16 that Figure 4 shows that "increasing amounts of unlabelled Factor VIII [added to a fixed concentration of labeled Factor VIII] resulted in dose-dependent inhibition of hydrolysis…by anti-Factor VIII IgG" is not agreed with. Figure 4 shows that when more Factor VIII is added the rate of hydrolysis increases, not decreases. If the examiner has mischaracterized this then applicant should point this out in detail. At any rate, these 3 peptide are not Factor VIII and applicants have not shown that these peptides would inhibit the activity of the antibody or any other utility.

Claims 111-113 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claims 86, 106, 108-110, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 86 is confusing and indefinite in the recitation of "said Factor VIII has effectively been degraded..." on lines 8-9. What is meant by "effectively". Is it meant to be any degradation that can be shown e.g. on a PAGE gel, that Factor VIII has been completely degraded, that Factor VIII no longer has any activity in the clotting process, some intermediate between these states, etc.?

Claims 106, 108 and 109 are indefinite in the recitation of "such as". It is not known whether this limitation is meant to be limiting or simply illustrative.

Claim 110 is indefinite in the recitation of "said sequencing". There is no antecedent basis for this phrase in claim 104.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 114-116, 121-123 and 141-143 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The instant claims are drawn to analogs of the three peptide sequences that are presumably the cleavage sites for the anti-Factor VIII allo-antibody. The specification does not teach that an analog has been made nor that this analog will inhibit the activity of the antibody. Furthermore the specification does not teach which analogs should be made and used. Therefore,

the specification does not enable one of ordinary skill in the art to make and/or use analogs as in the instant claims.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 111-113 are rejected under 35 U.S.C. 102(b or e) as being anticipated by Ill, et al. (A), Lollar, et al. (B) or Voorberg (C). Ill, et al. teach SEQ ID NO:1-3 at residues 392-398, 820-826 and 934-940, respectively of SEQ ID NO:3. Lollar, et al. teach SEQ ID NO: 1 at residues 1-7 of SEQ ID NO:4 and SEQ ID NO:2-3 at residues 1681-1687 and 1795-1801 of SEQ ID NO:2, respectively. Voorberg teaches SEQ ID NO:1-3 at residues 392-398, 1010-1016 and 1124-1130 of SEQ ID NO:2, respectively.

Claims 151-154 are rejected under 35 U.S.C. 102(b) as being anticipated by either of Fulcher, et al. (U), Gilles, et al. (V), Fijnvandrast, et al. (W), Saenko, et al. (X and U-1) or Goldsmith (V-1). Fulcher, et al., Gilles, et al., Fijnvandrast, et al., Saenko, et al. (U-1) and Goldsmith each teach an anti-Factor VIII allo-antibody in at least the abstract. Saenko, et al. (X) teach the antibody in at least the last full paragraph on page 11601.

The instant claims are drawn to the antibody (1) which has catalytic activity, (2) is obtainable by the method of claim 86 and (3) that cleaves certain bonds. The catalytic activity is an inherent characteristic and does not affect the patentability of the product *per se*. Likewise the particular bonds that it cleaves is an inherent characteristic. Claim 152 states that the antibody is "obtainable" by the method of claim 86, which method assays for degradation of Factor VIII. However, the antibody may be obtained from other sources and still meet the requirements of the instant claim.

Claims 117-120 are allowed. Claims 87-105 and 107 are objected to as being dependent upon a rejected base claim.

Copies of Fulcher, et al. (U), Gilles, et al. (V), Fijnvandrast, et al. (W) and Saenko, et al. (X and U-1) are not being sent because they were cited in the corresponding PCT search report.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles L. Patterson, Jr., PhD, whose telephone number is 571-272-0936. The examiner can normally be reached on Monday - Friday from 7:30 to 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or

Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Charles L. Patterson, Jr.
Primary Examiner
Art Unit 1652

Patterson
September 8, 2004